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Paper 8
Date: October 4, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOLOGIC, INC.,
Petitioner,

v.

ENZO LIFE SCIENCES, INC.,
Patent Owner.

Case IPR2016-00822
Patent 7,064,197 B1

Before MICHAEL J. FITZPATRICK, ZHENYU YANG, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner, Hologic, Inc., filed a Petition to institute an *inter partes* review of claims 17, 19, 25, 105, 106, 113, 114, 116, 119, 120, 128–131, 150–152, 154, 178, 180, 185–187, and 189 of U.S. Patent No. 7,064,197 B1 (Ex. 1001, "the '197 patent") pursuant to 35 U.S.C. § 311(a). Paper 3 ("Pet."). Patent Owner, Enzo Life Sciences, Inc., filed a Preliminary Response pursuant to 35 U.S.C. § 313. Paper 7 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). Upon consideration of the Petition, and for the reasons explained below, we determine that the information presented shows a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged. *See* 35 U.S.C. § 314(a). We grant the Petition to institute an *inter partes* review.

A. Related Matters

Petitioner has filed an additional petition to institute an *inter partes* review of the '197 patent, in which it challenges other claims of the patent. *See* IPR2016-00820.

The parties identify the following lawsuits as involving the '197 patent: *Enzo Life Sciences, Inc. v. Hologic, Inc.*, No. 1:15-cv-271 (D. Del.); *Enzo Life Sciences, Inc. v. Siemens Healthcare Diagnostics, Inc.*, No. 1:12-cv-505 (D. Del.); *Enzo Life Sciences, Inc. v. Affymetrix, Inc.*, No. 1:12-cv-433 (D. Del.); *Enzo Life Sciences, Inc. v. Agilent Technologies Inc.*, No. 1:12-cv-434 (D. Del.); *Enzo Life Sciences, Inc. v. Illumina Inc.*, No. 1:12-cv-435 (D. Del.); *Enzo Life Sciences, Inc. v. Abbott Laboratories et al.*, No.

1:12-cv-274 (D. Del.); *Enzo Life Sciences, Inc. v. Becton Dickinson and Company et al.*, No. 1:12-cv-275 (D. Del.); *Enzo Life Sciences, Inc. v. Life Technologies Corp.*, No. 1:12-cv-105 (D. Del.); and *Enzo Life Sciences, Inc. v. Roche Molecular Systems Inc. et al.*, No. 1:12-cv-106 (D. Del.). Pet. 2–3; Paper 6, 1–2.

B. The '197 Patent

The '197 patent relates generally to the detection of genetic material by polynucleotide probes. Ex. 1001, 1:23–24. The '197 patent refers to the material to be detected as an analyte. *Id*. at 1:37–39. An analyte may be present in a biological sample such as a clinical sample of blood, urine, saliva, etc. *Id*. at 5:47–50. If an analyte of interest is present in a biological sample, it is fixed, according to the invention of the '197 patent, in hybridizable form to a solid support. *Id*. at 5:58–60. The '197 patent states that it is preferred, and all of the challenged claims require, that the solid support be non-porous. *Id*. at 6:2–6; *e.g.*, *id*. at 15:51–53 (claim 17 reciting a "non-porous solid support").

> Chemically-labeled probes are then brought into contact with the fixed single-stranded analytes under hybridizing conditions. The probe is characterized by having covalently attached to it a chemical label which consists of a signaling moiety capable of generating a soluble signal. Desirably, the polynucleotide or oligonucleotide probe provides sufficient number of nucleotides in its sequence, e.g., at least about 25, to allow stable hybridization with the complementary nucleotides of the analyte. The hybridization of the probe to the single-stranded analyte with the resulting formation of a double-stranded or duplex hybrid is then detectable by means of the signalling moiety of the chemical label which is attached to the probe portion of the resulting hybrid. Generation of the soluble signal

> provides simple and rapid visual detection of the presence of the analyte and also provides a quantifiable report of the relative amount of analyte present, as measured by a spectrophotometer or the like.

Id. at 6:15–32.

C. The Challenged Claims

Petitioner challenges claims 17, 19, 25, 105, 106, 113, 114, 116, 119, 120, 128–131, 150–152, 154, 178, 180, 185–187, and 189. Pet. 1. Independent claims 17, 19, and 25 are illustrative and reproduced below.

> 17. An array comprising various single-stranded nucleic acids fixed or immobilized in hybridizable form to a non-porous solid support.
>
> 19. An array comprising single-stranded nucleic acids fixed or immobilized in hybridizable form to a non-porous solid support.
>
> 25. An array comprising various single-stranded nucleic acids fixed or immobilized in hybridizable form to a non-porous solid support having wells or depressions.

All of the remaining claims that are challenged depend directly from at least one of independent claims 17, 19, and 25, with several of them in multiple dependent form.

D. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

References	Basis[1]	Claims Challenged
Fish (Ex. 1006)[2]	§ 102(b)	17, 19, 25, 105, 106, 114, 116, 119, 128, 129, 131, 150, 152, 178, 180, 186, and 187
Fish	§ 103(a)	130, 131, 151, and 154
Fish, Metzgar (Ex. 1009),[3] and Sato (Ex. 1034)[4]	§ 103(a)	120 and 189
Fish and Gilham (Ex. 1019)[5]	§ 103(a)	113 and 185
VPK (Ex. 1008)[6] and Metzgar	§ 103(a)	17, 19, 25, 105, 106, 114, 119, 120, 128, 129, 131, 150–152, 178, 180, 186, and 189

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, took effect on March 18, 2013. Because the application from which the '197 patent issued was filed before that date, our citations to 35 U.S.C. §§ 102 and 103 are to their pre-AIA version.
[2] Falk Fish, et al., "A Sensitive Solid Phase Microradioimmunoassay For Anti-Double Stranded DNA Antibodies," *Arthritis and Rheumatism*, Vol. 24, No. 3, 534–43 (March 1981).
[3] U.S. Patent No. 3,572,892, issued Mar. 30, 1971.
[4] Sato et al., "Cell Surface Charge and Cell Division in Escherichia coli after X irradiation," Radiation Research 87, 646–56 (1981).
[5] P. T. Gilham, "Immobilized Polynucleotides and Nucleic Acids," *Immobilized Biochemicals and Affinity Chromatography*, 173–85 (1974).
[6] A. C. Van Prooijen-Knegt, et al. "In Situ Hybridization of DNA Sequences in Human Metaphase Chromosomes Visualized by an Indirect Fluorescent Immunocytochemical Procedure," *Experimental Cell Research*, Vol. 141, 397–407 (Oct. 1982).

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